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SHAUGHNESSEY NO.

10  
REVIEW NO.

EEB REVIEW

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TYPE PRODUCT(S) : I, D, H, F, N, R, S Synthetic Pyrethroid

DATA ACCESSION NO(S). \_\_\_\_\_

PRODUCT MANAGER NO. G. LaRocca (15)

PRODUCT NAME(S) Danitol 2.4 EC

COMPANY NAME Sumitomo Chemical America, Inc.

SUBMISSION PURPOSE Submission of data in response to  
previous review.

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
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## EEB REVIEW

### Danitol (Fenpropathrin)

#### 100 Submission Purpose

With this submission the registrant, Sumitomo Chemical America, Inc., has provided an aquatic invertebrate life-cycle study. Furthermore, they request an update on data requirements for registering Danitol.

#### 101 Hazard Assessment

##### 101.1 Discussion

Additional mammalian toxicity data were obtained from Toxicology Branch.

<u>Species</u>	<u>Test Type</u>	<u>Test Mat.</u>	<u>Results</u>
rat	subacute feeding	batch #24	100% mort. by day 20 at 900 ppm
rat	90-day feeding	fenpropathrin	NOEL=300 ppm LEL=600 ppm
rat	90-day feeding	96.0%	NOEL>250 ppm
dog	90-day feeding	96.2%	NOEL>250 ppm
rat	3-generation rep.	97.0%	NOEL=25 ppm LEL=250 ppm Test levels: 0, 5, 25, and 250 ppm
rat	metabolism	<sup>14</sup> C-labelled fenpropathrin	97% eliminated in 48 hours

These data show that mammals are not likely to be acutely affected at levels less than 250 ppm.

## 101.2 Likelihood of Adverse Effects to Non-Target Organisms

The following measured residue data were taken from Residue Chemistry Branch reviews.

<u>Vegetation</u> <u>type</u>	<u>Application</u> <u>no.</u>	<u>rate(lbs a.i./a)</u>	<u>days</u> <u>PHI</u>	<u>Measured</u> <u>residues(ppm)</u>	<u>RCB review</u> <u>date</u>
cotton leaves	4	0.2	66	2.77	10/23/84
boll cases	4	0.2	66	0.093	10/23/84
cotton seed kernels/ hulls	4	0.2	66	0.53	10/23/84
grapes	4	0.2	21	0.9	4/10/85
apples	3-10	0.4 0.8	14 14	0.46-3.2 3.4 -4.2	1/12/84 1/12/84
pears	3-6	0.5	14	3.0	1/12/84

The 1/12/84 RCB review also indicated that there was little correlation between pre-harvest interval and residue levels suggesting that the levels do not decline over time.

Compare these measured values with estimations of residues on various vegetation types based on the nomograph developed after Kenaga, E. E. (1973) Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Birds in their Environment. In Environmental Quality and Safety, Global Aspects of Chemistry, Toxicology and Technology as Applied to the Environment, Vol. II. George Theime Publishers.

### Estimated Residues in PPM at 0.2 lbs. a.i./acre (X4 appl.)

	<u>short</u> <u>grass</u>	<u>long</u> <u>grass</u>	<u>leafy</u> <u>crops</u>	<u>insects</u> <u>forage</u>	<u>seed</u> <u>Pods</u>	<u>fruit</u>
Max-immed.	48(192)	22(88)	25(100)	12(48)	2(8)	1(4)
Typ-immed.	25(100)	18(72)	7(28)	7(28)	0.6(2.4)	0.3(1.2)
Max-6 week	6(24)	4(16)	4(16)	0.2(0.8)	0.3(1.2)	0.3(1.2)
Typ-6 week	1(4)	1(4)	<0.2(.8)	<0.2(.8)	<0.02	<0.04(.16)

Considering that the maximum measured residue on fruit after 3-10 treatments at 0.4 lbs ai/acre was 3.2 ppm, the estimated residue on fruit after 4 treatments at 0.2 lbs ai/acre of 4 ppm is somewhat high (3-4 times). However, the estimated levels on some vegetation types are 3 to 4 times the 3-generation rat NOEL of 25 ppm. Based on this, it is not possible to eliminate chronic effects to mammals as a concern, more data are needed.

### 101.3 Data Submitted

The aquatic invertebrate study resulted in an MATC of  $>0.22$  ppb  $<0.35$  ppb. All Daphnia magna died by day 19 at 0.35 ppb. Fecundity was decreased at 0.35 ppb even before all adults died. The study is core, it fulfills the guideline (72-4) requirement for an aquatic invertebrate life-cycle test.

### 103. Conclusions

The registrant requested that EEB indicate the outstanding data requirements for Danitol. The following data are still required by EEB before Danitol will be considered for registration review for any use:

1. Reproductive tests with two species of birds, an upland gamebird and a waterfowl;
2. A fish full life-cycle test. (Protocol reviewed and approved);
3. Fish bioaccumulation test results, the one submitted was invalid (Feb. 3, 1986, EAB review); and
4. Field testing to show safety to aquatic organisms (Protocol under review).
5. EEB is concerned with the possible chronic hazard to mammals based on a comparison with the available reproductive No Observed Effect Level and estimated exposure levels on terrestrial food items. If the registrant wants to show that this chronic hazard will not occur, they must either provide reproductive test results with mammals showing a more precise reproductive NOEL or they must provide actual residue data of terrestrial wildlife food items in the field following multiple applications at the maximum application rate. This study must show residues on various terrestrial food items immediately after application and over time until the residues decline to less than 25 ppm. The registrant must submit a protocol to EPA for review and approval before conducting this study.

The shrimp study (Acc # 249939, performed by EG & G Bionomics July, 1981, was categorized as invalid by R. Farringer July 21, 1983. The rationale was low DO at 96 hours, erratic dose/mortality response, and unusually high mortality in the solvent control. Also, EEB does not have an acute mollusc study for Danitol. The following estuarine studies are required before Danitol may be considered for registration on cotton or other use sites involving estuarine exposure:

1. Shrimp 96-hour acute toxicity test;
2. Either a mollusc 96-hour shell deposition EC50 test or a mollusc 48-hour embryo-larve EC50; and
3. Shrimp life-cycle test.

Other data may be required depending on the results of the requested tests and specific uses. For example, mammalian biological field studies may be required depending on the results of the requested mammalian reproduction test or the residue monitoring study.

EEB considers the use of Danitol to be extremely hazardous to the environment. The above list of data consists of the minimum requirements needed to either show safety or characterize the environmental hazard of Danitol. The field tests are not an end in themselves, they must show safety or they must quantify the adverse effects.

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Daniel Rieder, Wildlife Biologist  
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DATA EVALUATION RECORD

1. Chemical: Danitol/Sha # 127901
2. Test Material: Technical fenpropathrin, radio-labeled,  
98% pure
3. Study Type: Aquatic Invertebrate life-cycle  
Species Tested: Daphnia magna
4. Study ID: Forbis, Alan D., David Burgess, and Brenda Bunch.  
1985. Chronic Toxicity of (cyclopropyl-1-<sup>14</sup>C)  
fenpropathrin to Daphnia magna Under Flow-through  
Test Conditions. Conducted at Analytical Bio-  
Chemistry Laboratories, Inc. Report # 32547.  
September 9, 1985. Submitted to EPA by Sumitomo  
Chemical America, Inc. Acc. No. 259678.

5. Reviewed By:

Daniel Rieder  
Wildlife Biologist  
EEB/HED

Signature: Daniel Rieder

Date: 4/10/86

6. Approved By:

Norm Cook  
Supervisory Biologist  
EEB/HED

Signature: Norman Cook

Date: 9-15-86

7. Conclusions:

This study is scientifically sound and fulfills the guideline requirements for an aquatic invertebrate life-cycle test with technical Danitol. This test resulted in an MATC interval of 0.22 to 0.35 ppb (measured concentration). All daphnids died in the measured concentrations of 0.35 ppb and 1 ppb. There was apparently reduced reproduction at the 0.35 ppb test level before all the daphnids died (by day 19).

8. Recommendations: N/A

*Sam*

9. Background: This study was submitted to fulfill registration data requirements.
10. Discussion of Individual Test: N/A
11. Materials and Methods

The test organisms, Daphnia magna were obtained from inhouse cultures. They were held at  $20 \pm 2^\circ\text{C}$ . Lighting was 50-70 footcandles at 16 hours daylight per 24 hours. Ten first instar (<24 hrs. old) daphnids were tested per test container. There were 4 test containers used per level (40 Daphnia magna per level).

The system contained seven sets (5 concentrations, and solvent and untreated control) of four replicate, one-liter glass beakers. A half-liter proportional diluter apparatus was used for intermittent introduction of [cyclopropyl-1- $^{14}\text{C}$ ] fenpropathrin and dilution water into test chambers. Test chambers were immersed in temperature controlled water bath ( $20 \pm 2^\circ\text{C}$ ).

The test material used in the range finding tests was technical grade fenpropathrin (lot # SX-1558) listed as about 90% pure. The life-cycle test material was radio-labeled Fenpropathrin-[cyclopropyl-1- $^{14}\text{C}$ ]. The radio purity was measured at greater than 98%.

The solvent was acetone.

The nominal test concentrations were: 0.072, 0.12, 0.24, 0.43 and 1.0 ppb. Test levels were measured on days 0, 4, 7, 14, and 21. Dosing lasted 21 days. The test solutions were replaced about 3 times every 24 hours.

Survival and abnormal effects were record Monday, Wednesday, and Friday, each week. A daphnid was considered dead with the cessation of all movement. Abnormal effects monitored were daphnids on the bottom, erratic swimming, and loss of equilibrium. Reproduction success was measured by counting (and discarding) all offspring (whether dead or alive) each Monday, Wednesday, and Friday.

The statistics used included subjecting parameter measurements (adult length, survival, and total young/adult/reproduction day to a oneway analysis of variance. When treatment effects were indicated following a significant F-test of the mean square ratio's, a multiple means comparison test, Fisher's protected Least Significant Difference (LSD) test, was used to determine which exposure levels differed from control values.

Arcsin transformation was performed on survival data to obtain normally distributed values. All differences were considered significant at the  $\alpha = 0.05$  level (95% Confidence level).

Total young/adult/reproduction day of each replicate was calculated in the following manner:

$$\frac{\text{Total number of young produced}}{(\text{Total number of adults}) \times (\text{Reproduction days})}$$

## 12. Reported Results:

A 48-hour static and 7-day flow-through preliminary range-finding study indicated the LC<sub>50</sub> of fenpropathrin was between 0.5 and 2 ppb. The mean measured concentrations (0.064, 0.10, 0.22, 0.35, and 1.0 ppb) were 81 to 100% of nominal levels (0.072, 0.12, 0.24, 0.43, and 1.0 ppb). Survival at the 0.35 and 1.0 ppb level was significantly different from the control. All daphnids were dead after 7 days in the 1 ppb test concentration and after day 19 in the 0.35 ppb level.

One way analysis of variance showed no difference in adult lengths between levels where organisms survived (0.064, 0.10, and 0.22 ppb) and the untreated control.

There was a significant decrease in fecundity (mean young/adult/reproduction day) after 21 days at the 0.35 and 1.0 ppb levels.

Table 1 shows measured concentrations, table 2 shows water quality measurements, and table 3 presents the survival, fecundity, and adult length.

## 13. Study Author's Conclusions:

MATC > 0.22 < 0.35 ppb measure concentrations.

0.35 ppb is lethal to daphnids exposed 19 days.

## 14. Reviewer's Discussion and Interpretation of the Study

### A. Test Procedures:

The test procedure was acceptable, however two minor problems were noted. The percent of solvent used in the solvent control and treatment containers was not identified. Table 1, characteristics of well water, was missing from the report.



B. Statistical Analysis: By reviewing the data from the study, it is apparent that the MATC is accurate.

C. Discussion/Results:

This study shows that exposure levels of 0.35 ppb will not only cause reduced fecundity in less than 19 days compared to controls but will cause 100% mortality after 19 days exposure.

D. Adequacy of Study: Core

15. Completion of One-Liner: Completed

16. CBI Appendix: N/A

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\_\_\_\_ Description of quality control procedures.

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\_\_\_\_ Sales or other commercial/financial information.

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☒ FIFRA registration data.

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